

CROMOLYN SODIUM- cromolyn sodium spray, metered
Bausch & Lomb Incorporated

Cromolyn Sodium Nasal Solution USP
NASAL SPRAY

(Adults and children 2 years and older)

Active ingredient (per spray)

Cromolyn sodium 5.2 mg

Purpose

Nasal allergy symptom controller

Uses

to prevent and relieve nasal symptoms of hay fever and other nasal allergies:

- runny/itchy nose
- sneezing
- allergic stuffy nose

Warnings

Do not use

- if you are allergic to any of the ingredients

Ask a doctor before use if you have

- fever
- discolored nasal discharge
- sinus pain
- wheezing

When using this product

- it may take several days of use to notice an effect. Your best effect may not be seen for 1 to 2 weeks.
- brief stinging or sneezing may occur right after use
- do not use it to treat sinus infection, asthma, or cold symptoms
- do not share this bottle with anyone else as this may spread germs

Stop use and ask a doctor if

- shortness of breath, wheezing, or chest tightness occurs
- hives or swelling of the mouth or throat occurs

- your symptoms worsen
- you have new symptoms
- your symptoms do not begin to improve within two weeks
- you need to use for more than 12 weeks

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- see package insert on how to use pump
- parent or care provider must supervise the use of this product by young children
- adults and children 2 years and older:
 - spray once into each nostril. Repeat 3-4 times a day (every 4-6 hours). If needed, may be used up to 6 times a day.
 - use every day while in contact with the cause of your allergies (pollen, molds, pets, and dust)
 - to **prevent** nasal allergy symptoms, use before contact with the cause of your allergies. For best results, start using up to one week before contact.
 - if desired, you can use this product with other medicines, including other allergy medicines.
- Children under 2 years: Do not use unless directed by a doctor.

Other information

- store between 20°– 25°C (68°– 77°F)
- protect from light
- keep carton and package insert. They contain important instructions.

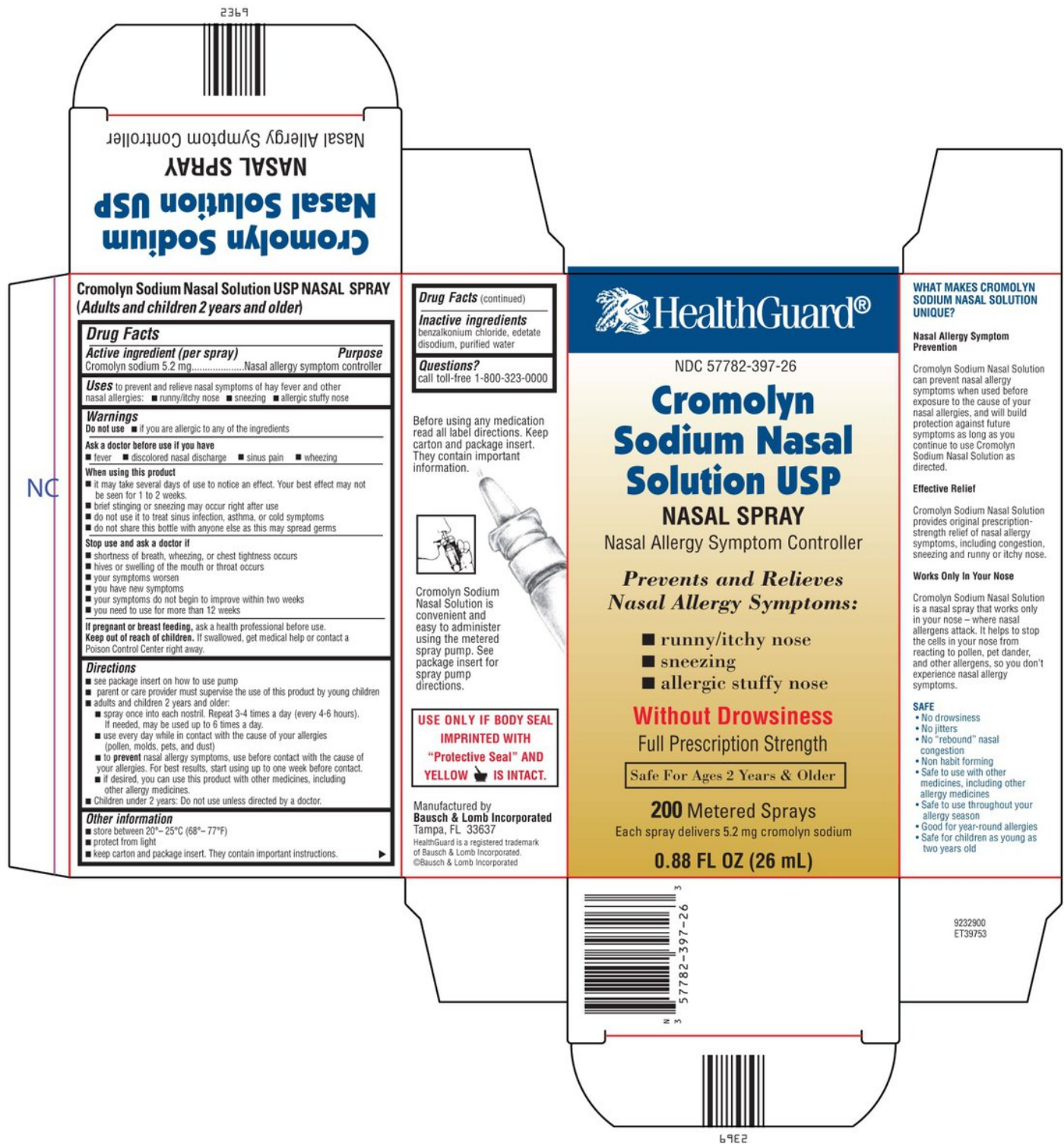
Inactive ingredients

benzalkonium chloride, edetate disodium, purified water

Questions?

call toll-free 1-800-323-0000

Package/Label Principal Display Panel



HealthGuard

NDC 57782-397-26

Cromolyn Sodium Nasal Solution USP

NASAL SPRAY

Nasal Allergy Symptom Controller

Prevents and Relieves Nasal Allergy Symptoms:

runny/itchy nose

sneezing

allergic stuffy nose

Without Drowsiness

Full Prescription Strength

Safe For Ages 2 Years & Older

200 Metered Sprays

Each spray delivers 5.2 mg cromolyn sodium

0.88 FL OZ (26 mL)

CROMOLYN SODIUM				
cromolyn sodium spray, metered				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		NASAL	NDC:57782-397	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CROMOLYN SODIUM (UNII: Q2WXR1I0PK) (CROMOLYN - UNII:Y0TK0FS77W)			CROMOLYN SODIUM	5.2 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57782-397-26	1 in 1 CARTON	07/03/2001	
1		26 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA075702	07/03/2001	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment			
Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(57782-397)

Establishment			
Name	Address	ID/FEI	Business Operations
Cambrex Profarmaco Milano Srl		438051401	API MANUFACTURE(57782-397)

Establishment			
Name	Address	ID/FEI	Business Operations
Aventis Pharma Manufacturing Pte LTD.		595299306	API MANUFACTURE(57782-397)

Revised: 12/2017

Bausch & Lomb Incorporated